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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/006,400	11/30/2001	Richard S. Ginn	267/121	4276

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EXAMINER

DAWSON, GLENN K

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 07/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/006,400

Applicant(s)

GINN, RICHARD S.

Examiner

Glenn K. Dawson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 April 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-16, 21-32, 38-42, 46-51 and 54-79 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 21-26 and 63-78 is/are allowed.
- 6) ☒ Claim(s) 11, 14, 15, 27-31, 40-42, 47-51, 56-62 and 79 is/are rejected.
- 7) ☒ Claim(s) 12, 13, 16, 32, 38, 39, 46, 54 and 55 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 November 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 11,14,15,27,28,40,42,47,48,51,56-62 and 79 are rejected under 35 U.S.C. 102(b) as being anticipated by Green, et al.-EP 0 774 237.

Green discloses a device and method for closing a hole in a vessel wall, including an elongate member (100 or 20, depending on the claim), a clip 22, a locator member 60 having a deflectable member 62b, 64b and a control element 68 moved by an actuator 75. Axial movement of the control element causes the deflectable element to buckle outwards to allow it to anchor against the inner vessel wall. Following anchoring, tube 22 is pushed distally to cause the clip to engage and pierce tissue and close the passage. This procedure is performed following a catheterization procedure where a catheter would be placed through an introducer into the vessel and an angiographic or angioplasty procedure is performed in the vessel and then the above device is used to close the passage.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 29-31, 41, 49 and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Green, et al.-'237.

Green discloses the invention as claimed with the exception of the passage of the instruments through the lumen of the elongate member to perform a therapeutic procedure and the timing of the introduction of the locator member.

Since Green discloses that the therapeutic instruments are placed through an introducer, it would have been obvious to have placed them through introducer 100 in order to eliminate the unnecessary use of a second introducer. To have placed the locator into the lumen of the tubular member before the introducer is advanced through the passage would have been an obvious step to perform as the timing of doing so is irrelevant, and applicant has not disclosed why such a timing is critical and would solve a stated problem or is for a particular purpose, and placing it into the lumen before, during or after the tubular members' introduction into the passage would not have provided an advantage over either of the other times.

Drawings

The drawings submitted on 11-08-2004 are approved by the examiner.

Allowable Subject Matter

Claims 21-26 and 63-78 are allowed.

Claims 12, 13, 16, 32, 38, 39, 46, 54 and 55 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

Applicant's arguments filed 04-26-2005 have been fully considered but they are not persuasive.

The applicant's definition of "buckle" is deemed to be too narrow. While the definition states that "usually" it is in response to stress or force being applied, this is certainly not required. Therefore, the examiner contends that action which causes the splines to bend or warp or bulge is all that is necessary to read on the claimed limitations. Motion in a proximal direction causes the splines to bend from a rounded shape to more of a linear shape. This is a "buckling" of the splines. Movement on a distal direction causes the shape memory material of the splines, in the absence of a constraining force, to "buckle" outwards to an expanded configuration.

If the entirety of the splines changes shape, then clearly the intermediate portion does so as well.

The clip of Green clearly has tines, as shown in fig. 17 and 22. The clip is essentially annular in shape noting fig. 4. The tines do extend substantially axially and distally as shown in fig. 2.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Glenn K. Dawson whose telephone number is 703-308-4304. The examiner can normally be reached on M-Th 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan T. Nguyen can be reached at 571-272-4963. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Glenn K Dawson
Primary Examiner
Art Unit 3731

gkd
19 July 2005